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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,651	11/29/2006	Heno Perillo	4705-0120PUS1	5789
2292 7590 08/31/2010 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER				
FINN, MEGHAN R				
ART UNIT		PAPER NUMBER		
1614				
NOTIFICATION DATE		DELIVERY MODE		
08/31/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/580,651

Applicant(s)

PERILLO ET AL.

Examiner

MEGHAN FINN

Art Unit

1614

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44-56 is/are pending in the application.
- 4a) Of the above claim(s) 47-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 44-46, 54-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI.08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Interval Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Applicant's Amendment filed June 11, 2010 has been received and entered into present application. No claims were canceled and claims 54-56 were added by applicant. Claims 47-53 remain withdrawn and thus claims 44-46 and 54-56 are pending.

Applicants' arguments, filed June 11, 2010, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Declaration

The Declaration under 37 C.F.R. 1.132 by Mr. Heno Perillo submitted on June 11, 2010 has been considered however was not deemed enough to overcome the obviousness rejection of record. Further explanation of the reasoning is below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 44-46 and 54-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (US 5,378,475) in view of Harris et al. (US 4,670,258) in further view of Muller et al. (US 6,027,776), each already of record, for the reasons set forth at pages 3-5 of previous office action dated December 11, 2009, of which reasons are herein incorporated by reference.

Applicant has amended claim 44 such that it now reads upon the composition in any flexible bag and reads on gancyclovir in the free acid form and is no longer a product-by-process claim. Applicant has also added new claims 54-56 which specify the same type of bag previously claimed in claim 44 and in claim 54 has claimed a product by process and specified the same process of claim 47. While applicant has modified the claims they have not introduced any new limitations that were not previously contained within claim 44. Thus claims 44-46 and 54-56 are rejected over Smith et al. in view of Harris et al. in further view of Muller et al. for the same reasons discussed in the previous office action.

Applicant argued that their gancyclovir is not the same as that of Smith et al. and points to the process of which their gancyclovir was made on page 6 of the specification. This does not prove that it is different from the gancyclovir from Smith et al. and applicant appears to be arguing that the gancyclovir of Smith et al. would contain alkaline residues without any factual evidence to support this assertion. There is no evidence that the gancyclovir obtained by Smith et al. in the free acid form from Syntex Laboratories (see column 12, example 2) has alkaline residues, and in the absence of such evidence the fact that applicant's compound was made in a different way is not enough to show a difference between the two compositions. Applicant has also submitted a declaration by Mr. Perillo, who states that it was the state of the prior art such that gancyclovir was recommended to be stable for 14 days under refrigeration and it should be used within 24 hours while their system is stable for 24 months and does not require refrigeration which is an unexpected result. Applicant has provided no factual evidence that their composition has different stability from the commercially available gancyclovir or the gancyclovir of Smith et al. The mere fact that the prior art may *recommend* refrigeration does not mean that it would not be stable at room temperature or that it is not stable for more than 24 hours. Thus, in the absence of some showing that applicant's composition is different or superior to that of Smith et al. or commercially available free acid form of gancyclovir there is no showing of unexpected results because applicant has not compared their invention to the closest prior art or any prior art.

Applicant's argument has been fully and carefully considered however is not deemed persuasive and thus the rejection of claims 44-46 is **maintained**. New rejection of claims 54-56 is necessitated by their addition to the claims.

Conclusion

Rejection of claims 44-46 is deemed proper and is **maintained**.

New rejection of claims 54-56 is necessitated by amendment.

No Claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 8:30am-6pm Mon-Thu, 8:30am-5pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

/James D Anderson/
Primary Examiner, Art Unit 1614